

Japan Pre-Entry Tuberculosis Screening - TECHNICAL INSTRUCTIONS

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Tuberculosis and Infectious Disease Control Division
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JAPAN PRE-ENTRY TUBERCULOSIS SCREENING TECHNICAL INSTRUCTIONS (JPETS-TI)

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1 Introduction to the pre-entry TB screening program for Applicants of the Certificate of Eligibility / visa for mid- to long-term stay

- This document is intended to provide technical guidance to those who are authorized by the Government of Japan to conduct tuberculosis (TB) screening under the Immigration Control and Refugee Recognition Act of Japan, which states that any alien who is diagnosed with active TB shall be denied permission for landing in Japan.
- Advice on the interpretation of any specific detail of the Technical Instructions can be obtained on the website. Do not send X-ray film or applicant personal identifiable information.
- Throughout this document, “screening” should be interpreted as the process of examination as to whether applicants for Certificate of Eligibility or visa for mid- to long-term stay in Japan (the “Applicant”) are assessed for active TB.
- The purpose of TB screening is to detect the suspected presence of active TB, as well as to contribute to Applicants’ health and TB control in the countries of Applicants’ nationality by, early diagnosis and appropriate treatment of TB.
- TB is a disease caused by infection with a member of the *Mycobacterium tuberculosis* complex. It may exist as an active disease, with clinical signs or symptoms, or latent infection (i.e., Latent TB Infection, LTBI) where the infection has not progressed to active disease. This screening program is intended to identify bacteriologically-positive pulmonary, trachea-bronchial, pharyngeal and laryngeal TB. However, Applicants with any other form of active TB that requires TB treatment, if detected in the process of the screening, will be required to undergo and complete TB treatment before entry to Japan, which this screening program is not intended to identify. This screening program is NOT intended to identify LTBI. Details of criteria for suspecting active TB are described in section 3.
- The screening is applied to nationals of countries with a heavy caseload of TB patient diagnosed in Japan (China, Indonesia, Myanmar, Nepal, the Philippines and Vietnam) who wish to stay in Japan for over 3 months as mid- or long-term residents as prescribed in Article 19-3 of the Immigration Control and Refugee Recognition Act (except those with re-entry permission or those whose present address is OUTSIDE the above-mentioned countries etc.). However, the Government of Japan may, where appropriate, require any person seeking permission to enter to Japan other than above-mentioned applicants to be screened.

2 Role of an appointed physician of the Panel Clinics

- Screening of Applicants will be conducted by physicians who have been designated and registered by the medical facilities (“Panel Physicians”), which in turn have been designated by the Government of Japan (“Panel Clinics”). The Panel Clinics will provide the list of registered Panel Physicians to the Government of Japan, and also immediately if any change(s) are made to the list.
- Details of administrative arrangements for Panel Physicians and Panel Clinics are found in Annex A.
- A Panel Physician screens the Applicants as set out in the Technical Instructions. On occasions where the Panel Physician has determined that active TB is not present in an Applicant, the Panel Physician shall issue a TB clearance certificate (“the Certificate”)

specified by the Government of Japan. No Certificate will be issued if there is suspicion of active TB. In cases of doubt, it is the Panel Physician's responsibility to take necessary steps to resolve the issue (see Section 8).

- It is the personal responsibility of the Panel Physician to oversee the entire screening process of an Applicant, to confirm the identification of the Applicant, and to make a professional judgement as to whether the Applicant will be issued with a Certificate.
- On all occasions where active TB is found in an Applicant through the screening, the Panel Physician must ensure that the Applicant is given clear and unambiguous advice about the need to seek TB treatment immediately.
- On all occasions where drug-resistant cultures are reported by the laboratory (see Section 7) on any Applicant, the Panel Physician will share this with the medical facility where the Applicant shall receive TB treatment without delay.
- On all occasions where notification of active TB is required in the public health system by local law, the Panel Physician must also share the diagnosis of active TB to the local, regional or national authorities in the Applicant's home country and record this fact at the Panel Clinic that the Panel Physician belongs to.
- When diagnosis of active TB is confirmed after referral to another medical facility that offers diagnosis and treatment services in accordance with WHO diagnosis and treatment guidelines as well as any national TB protocol ("TB Treatment Facility"), the Panel Physician will request the physician-in-charge at the TB Treatment Facility to share this fact with the local health authority.

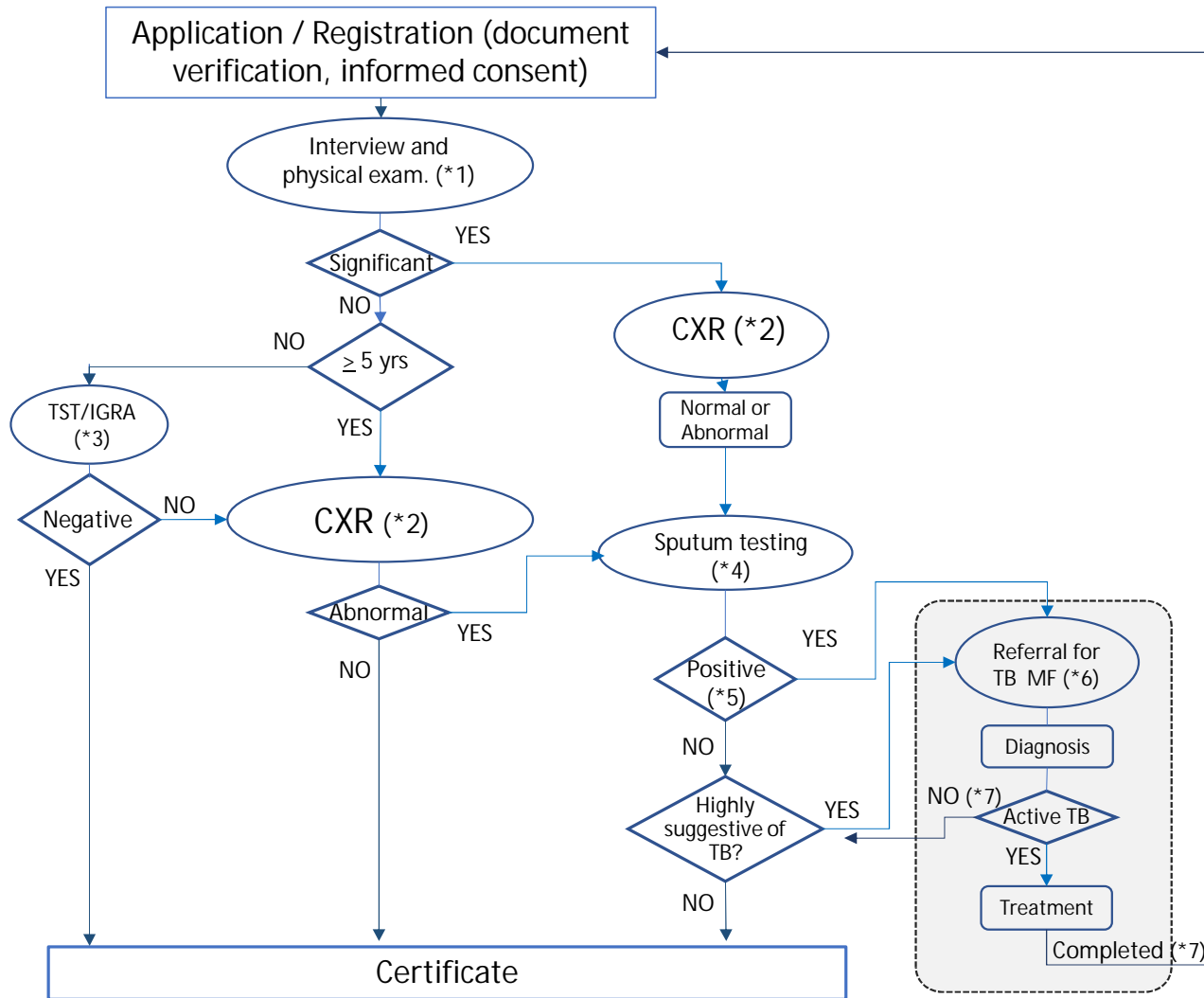
3 The screening process for TB in Applicants

1) General arrangements

- The Panel Clinic must be able to schedule an Applicant's appointment within 5 working days.
- The Panel Physician shall brief all Applicants on the purpose, nature and extent of the TB screening process. This may be with the use of information leaflets as necessary.
- The Applicant must complete an Informed Consent Form (see Section 4 and Annex E).
- Where Applicants are family members intending to travel together, the Panel Physician shall arrange for all the family members to be screened together as much as possible.
- A minor must be accompanied by a legal guardian.
* The definition of "a minor" shall be in accordance with the legislation of the Applicants' home country in which judicial decisions are made in the event of a dispute regarding the screening and obtaining consent.
- The screening is based on chest radiography ("CXR"). Other tests such as a Tuberculin Skin Test (Mantoux method) or Interferon Gamma Release Assay (IGRA) are not acceptable alternatives to CXR even when the Applicant is prepared to pay for such tests.

- Prior receipt of the Bacille Calmette-Guérin (BCG) vaccination does not change the screening process, requirements or required actions.
- If neither active nor old TB is suggested by the interview, physical examination, and CXR, it will be judged that the Applicant does not have active TB disease and the Certificate shall be issued.
- All Applicants suggested to have active or old TB by any of the interview, physical examinations and CXR, shall undertake the *Mycobacterium tuberculosis* test of three sputum specimens collected on each day for 3 consecutive working days (see “sputum examination”, Section 7)
- If any of the sputum test results suggest positive for *Mycobacterium tuberculosis* complex from an Applicant, the Applicant shall be diagnosed as having active TB and the Certificate shall NOT be issued.
- The Panel Physician is under no obligation to treat the Applicant - however, in case the Panel Physician agrees to carry out TB treatment, such treatment shall be in accordance with the WHO treatment guideline as well as any national TB protocol, using only quality assured drugs in accordance with the WHO’s recommended standards.
- In case the treatment is NOT given at the Panel Clinic, the Panel Physician must refer the Applicant to a medical facility which is capable of providing TB treatment according to the above-mentioned criteria (“TB Treatment Facility”).
- Regarding the process when active TB is suspected in spite of negative sputum test results, see Section 8.
- Overview of the screening process flow is shown in the figure below (JPETS algorithm).

JPETS algorithm



*1. For children < 15 yrs, include significant respiratory conditions (chronic respiratory disorders, history of lung surgery, etc.), see text.

*2. For pregnant women, see text.

*3. In case neither TST or IGRA is unavailable, see text.

*4. Sputum smear may be replaced with the WHO recommended NAATs such as Xpert MTB/RIF or Xpert MTB/RIF Ultra or TB-LAMP.

*5. Positive results either in smear (or the WHO recommended NAATs) or in culture.

*6. MF: Medical Facility for TB diagnosis and treatment.

*7. A report from MF is required in the prescribed format.

2) Screening categories and processes

There are different sets of screening items for the four categories of Applicants, namely adults (aged 15 years or over), pregnant women, children under 5 years old, and children aged from 5 to 14 years old.

General screening items

The screening includes the following for all Applicants. While the general screening items apply to all categories, there are some considerations in pregnant women and in children under 15 years old. See “medical record”, Annex F.

- Interview, which must collect information on the following:
 - Symptom(s) (e.g., cough, sputum expectoration, hemoptysis, weight loss, night sweats)
 - History of previous TB
 - *Information about the history of previous TB such as the date of diagnosis and treatment, TB treatment regimen, and the treatment outcome must be recorded.
 - History of close contact with a case of active pulmonary TB within the past two months, i.e., shared the same enclosed airspace, household or other enclosed environments frequently or over a prolonged period of days or weeks
- Physical examinations, which consist of the following:
 - Chest auscultation (breath sound)
 - Examinations of the neck (inspection, palpation)
 - Other examinations which the Panel Physician judges necessary.
- CXR (except for children under 5 years old)
- Sputum examination (for Applicants with suspicion of active TB based on the interview, physical examination and/or CXR)

Considerations in pregnant women

- During pregnancy, there is a small risk of radiation to the unborn baby, particularly in the first trimester. It is not recommended to take CXRs during the first trimester. Therefore, a pregnant woman has two options;
 - (1) Postpone the CXR (and the application process) until after delivery
 - (2) Continue with CXR with double shielding
- Regardless of the options, it is essential that the woman is counseled and informed consent is obtained and kept with the Applicant’s record about this appropriately.
- As a special measure, if a pregnant woman has taken CXR within the last three months at the same Panel Clinic in which she is receiving TB screening, the previous CXR may be used for clearance purposes provided that she meets both of the following two conditions; (1) she has no signs or symptoms of TB and (2) she has no close contact with an active pulmonary TB patient. No CXR taken in any other clinic may be used, nor any other screening test.

Considerations in children under 5 years old

- If interview and/or physical examination indicate suspicion of active TB, children under 5 years old must undergo CXR, as with adults.
- However, children under 5 years old who do not have signs and symptoms of active TB, AND history of TB, AND history of close contact with an infectious active pulmonary TB patient, the children must undergo a Tuberculin Skin Test (Mantoux method) or Interferon-Gamma Releasing Assay (IGRA). Judgment of TST results should follow the guidelines of US CDC or the national TB guidelines. IGRA results

should be judged according to criteria provided by the manufacturer. TST or IGRA results must not be regarded as negative in cases which TST or IGRA results are indeterminate or in cases which both tests are unavailable. If the TST (or IGRA) indicates negative, the Certificate will be issued. If either TST or IGRA does not indicate negative, the children undergo CXR. If the CXR does not indicate abnormal findings, then the Certificate will be issued. If the CXR indicates abnormal findings, then the children will undergo a sputum examination, as with adults (see Section 7).

- If a child under 5 years old has any chronic respiratory disease or a history of previous thoracic surgery or cyanosis, or respiratory insufficiency that limits activity, the Panel Physician shall have the discretion to carry out a sputum examination regardless of the CXR findings.
- If a child under 5 years old is found to have LTBI but not active TB, the Certificate will be issued. However, the Panel Physician must record on the Certificate that the Applicant has LTBI, and recommend the Applicant's parent(s)/guardian(s) to consult a TB Treatment Facility in their home country before departure or a public health center in Japan after arrival.

Considerations in children from 5 to 14 years old

- General screening items are applied.
- If a child aged from 5 to 14 years old has any chronic respiratory disease or a history of previous thoracic surgery or cyanosis, or respiratory insufficiency that limits activity, the Panel Physician shall have the discretion to carry out a sputum examination regardless of the CXR findings.

3) Sputum examination

- A sputum examination consists of a sputum smear microscopic examination (or WHO recommended nucleic acid amplification tests (NAATs), e.g., Xpert[®]MTB/RIF or TB-LAMP, hereinafter referred to as "WHO recommended NAATs") and culture examination (see Section 7).
- Where the CXR is suggestive of either active or old TB, a sputum examination must be performed. Additionally, a sputum examination is required for individuals with signs or symptoms of active TB regardless of CXR findings.
- The Applicant is required to submit three sputum specimens collected on each day for 3 consecutive working days to the Panel Clinic or the laboratory appointed by the Panel Clinic.
- See Section 7 in case of difficulty in collecting sputum specimens.

4 Consent for Screening

- The Panel Physician may designate a person who will explain the Informed Consent to the Applicants but it is the responsibility of the Panel Physician to ensure that Applicants are given sufficient information about the screening in a language that they understand (or steps are taken to ensure they understand), opportunity to ask questions and time to reflect on answers given, and complete an Informed Consent Form before the screening process starts (see Annex E). Information provided to Applicants should cover the purpose of the TB screening, the entire screening process, its benefits and disadvantages such as serious risks associated with the screening and potential outcomes.
- Applicants are to be informed that they are entitled to withdraw their consent at any time

after signing the form, up to the completion of the TB screening. However, The Panel Physician or the explainer must explain to Applicants that the certificate will not be issued if Applicants do not accept examination instructed by Panel Physician, which may obstruct the application process for the Certificate of Eligibility /visa.

- The Panel Physician must ensure that Applicants also understand and accept that any screening results and any relevant personal information collected during the assessment process, including health records and CXR may be shared with the Government of Japan.
- Where the Applicant is a minor, the Informed Consent Form is only valid if it is signed by his/her legal guardian.
- Where the Applicant is mentally competent to give consent but is unable to sign the Consent Form for physical reasons, the Panel Physician or the person in charge should request an independent witness in order to confirm that the Applicant has given consent whether orally or non-verbally and to sign the form on behalf of the Applicant.
- The Panel Physician must retain the Informed Consent Form (Annex E) for three years and make the form available to the Government of Japan upon request.

5 Identification

- The Panel Physician holds the overall responsibility in the identification process of the Applicant.
- Identification of the Applicant must be verified by the Panel Physician or an appropriate staff member designated by the Panel Physician, at the following stages of the screening: registration, interview and physical examination, CXR, sputum collection, and issuance of the Certificate or referral to a TB Treatment Facility.
- The identification must include the Applicant's valid passport. If the Applicant does not possess a valid passport, it can be substituted by an identification document that is issued by official authorities of that country.
- At each stage as above-mentioned, the staff must take all reasonable steps to check the validity of the passport (or other relevant document) by ensuring that that the photograph and the date of birth are consistent with the appearance of the Applicant.
- When there are doubts as to the identity of the Applicant, the Panel Physician should request the Applicant to provide further documents to substantiate his or her identity and keep them on record. The Panel Physician must not issue the Certificate until the doubts are cleared.

6 Chest Radiography (CXR)

- CXR should be taken on the day when the Applicant is interviewed and receives a physical examination at the Panel Clinic.
- Applicants aged 15 years old and above should receive a standard postero-anterior view CXR. Applicants aged less than 15 years old should receive a standard lateral view CXR in addition to the postero-anterior view. Further detail of the radiological process is contained in Annex B.
- CXR should be digitally captured and the CXR image data be digitally managed.

- CXR image should be interpreted by a radiologist registered by the Panel Clinic (“Panel Radiologist”), and reviewed by the Panel Physician.
- The Panel Radiologist should record details of all abnormalities observed, whether due to TB or otherwise. Further guidance is included in Annex C.
- CXRs of any Applicants should be re-taken if the initial CXR image is suboptimal due to technical factors. The Applicant should not leave until the Panel Radiologist decides that no additional CXR images are required. The Panel Radiologist may request the Applicant to undergo further CXR from a different view at no additional cost.
- Documents on which the interpretation results of the CXR are recorded must contain the full name, date of birth and passport number of the Applicant, dates the image was taken and interpreted, and names of the Panel Radiologist and of the Panel Physician.
- In interpreting the findings of the CXR, the Panel Radiologist shall have the discretion to compare the results of the current CXR with any previous CXR taken for that Applicant, if taken before.
- Applicants without signs and symptoms and whose CXR are confirmed to be free of any radiological findings compatible with active or old TB* may be issued with a Certificate by the Panel Physician.
*Radiological findings compatible with active or old TB specifically refer to the findings number 3.1 – 3.6 and 4.1 - 4.9 on Annex C.
- Applicants with signs and symptoms and/or any radiological findings compatible with active or old TB (see above) shall NOT be issued with the Certificate and proceed to laboratory sputum testing (see Annex C and D).
- If CXR findings are indicative of other respiratory disorders than TB, e.g., cancer, the Panel Physicians must recognize their medical obligation and consider counselling with the Applicant and refer the Applicant to an appropriate medical institution. In such cases, the screening process will be held temporarily. Providing that the CXR is free of any radiological findings compatible with active or old pulmonary TB, the Certificate may be issued without sputum examination. However, even if another disease is suspected, the sputum examination must not be omitted when any signs, symptoms or CXR findings are compatible with active or old TB.
- The Panel Physician should record the following items when resuming the screening process after the results of medical treatment for other disease.
 - (1) Diagnosis or tentative diagnosis (other than active or old TB) suspected from CXR findings.
 - (2) Final diagnosis, and details of treatment if provided.
 - (3) Whether or not the sputum examination for TB was conducted and the results.

7 Laboratory examination for *Mycobacterium tuberculosis*

- Laboratory examination for active TB in the screening may only be conducted in laboratories set up within the Panel Clinic or in laboratories which have been designated for that purpose by the Panel Clinic (“Panel Laboratories”).
- Laboratory examination for active TB must consist of three acceptable sputum specimens collected on each day for 3 consecutive working days taken in the early morning.
- The Panel Physicians will issue the Certificate for the Applicant who underwent sputum examinations only when the results of culture examination for all the 3 sputum specimens

are negative.

- The Panel Physicians must promptly start TB treatment at the Panel Clinic or refer the Applicant to a TB Treatment Facility if any of the sputum examination results indicates positive, by either sputum smear or WHO recommended NAATs.

1) Specimen collection

- The Panel Physicians must either perform the sputum specimen collection on-site or arrange for it in a Panel Laboratory. Specimens taken in other locations (e.g., the Applicant's dwelling) must NOT be accepted.
- If the Panel Physician delegates this procedure to a nurse or an assistant, the Panel Physician remains accountable for the integrity of this part of the screening procedure.
- Sputum collection must commence within 7 days of the CXR.
- Specimens should securely and promptly be transported to the Panel Laboratory with appropriate provision for cool-chain integrity (no exposure to high temperature). Applicants should not be allowed to transport specimens themselves. If transportation takes more than one hour, specimens must be refrigerated (but not frozen). Specimens should be processed to start examination within 24 hours of the receipt by the laboratory.
- Applicants who are unable to produce sputum specimens are required to have alternative methods of sputum collection performed (e.g., sputum induction by hypertonic saline inhalation or aspiration of early morning gastric fluid) for their TB status to be established. A Certificate can NOT be issued to Applicants who have been requested to undertake a sputum examination but have failed to submit the necessary sputum specimens.
- Further details of the procedure for correct sputum collection is contained in Annex D.

2) Laboratory practice

- Each specimen must be examined by smear microscopy for acid-fast bacilli (AFB) by auramine stain or by Ziehl-Neelsen stain and by culture on liquid or solid media for mycobacteria. If organisms suspected of mycobacteria are detected from culture, it is essential to identify mycobacterial species at least up to the *M. tuberculosis* complex level. It is also acceptable to perform any of the WHO recommended NAATs once, instead of smear microscopy examinations of 3 sputum specimens, based on the National TB control program in the country. However, the WHO recommended NAATs cannot replace culture examinations of 3 sputum specimens.
- Specimens should be cultured for a minimum of six weeks in liquid media and eight weeks in solid media unless a positive result is obtained earlier. Results of culture, whether positive or negative, should be reported to the Panel Physician as soon as the results are known.
- Positive *M. tuberculosis* cultures shall undergo drug susceptibility testing (DST) in the Panel Laboratory in accordance with WHO guidelines. If any drug resistance is detected, the laboratory should report to the Panel Physician without delay. The DST results must also be shared with the physician in charge of TB treatment at the TB Treatment Facility immediately. For details, see Section 8.
- See Section 8 for cases where culture results are indeterminate (e.g., due to bacterial contamination) or where there is discrepancy between results from culture and smear microscopy or WHO recommended NAATs.

8 Outcome of screening

- For the Applicants who do NOT have any signs and symptoms suggesting active TB AND whose CXR is free of any radiological findings compatible with active or old TB, the Panel Physician shall issue the Certificate so that Applicants are entitled to apply for the Certificate of Eligibility / visa for mid to long-term stay.
- Applicants who refuse screening process shall NOT be issued with the Certificate.
- Where the Certificate is to be issued after sputum examinations, the result of sputum examinations must be recorded on the Certificate. The Government of Japan may also specify other items to be reported.
- For Applicants who have been diagnosed with active TB, either with an interview, physical examinations, CXR, or sputum examinations, the Certificate is NOT to be issued and the Panel Physician must give the Applicant clear and unambiguous advice about the need to start TB treatment immediately and start TB treatment at the Panel Clinic or refer the Applicant to a TB Treatment Facility (Annex G).
- In case that the results of sputum examination of three specimens are all indeterminate (due to bacterial contamination, for example), the Panel Physician should request the Applicants to collect and submit three sputum specimens for examinations. However, no additional costs shall be charged in such cases.
- For the Applicants who are judged to be suspicious of active TB with signs or symptoms or CXR findings despite of all negative sputum test results, the Panel Physician should write a referral letter for the Applicant to a TB Treatment Facility after providing adequate and sufficient explanation. In such cases, the Panel Physician will postpone the issue of the Certificate and the screening process. The Panel Physician may resume the screening process when the Panel Physician receives a diagnosis report (Annex Ia) indicating that the Applicant does not have active TB from the TB Treatment Facility.

TB treatment provided at the Panel Clinic

- When it is agreed that the Applicant receives TB treatment at the Panel Clinic, TB treatment shall be in accordance with the WHO treatment guideline as well as any national TB protocol, and other requirements of TB Treatment Facilities (See section 3).
- When the Applicant has completed the full course of TB treatment in the Panel Clinic, the physician in charge of overseeing the treatment at the Panel Clinic must complete the TB Treatment Completion Report (Annex Ib).
- The Applicant should restart the TB screening process at the same Panel Clinic, but not within six months of the previous examination, at an additional fee (the standard test fee). Under exceptional circumstance whereby the initial Panel Clinic is no longer able to provide the screening services, the Applicant may choose another Panel Clinic.
- The Panel Physician shall restart the TB screening process after confirming that the TB Treatment Completion Report (Annex Ib) indicates at least two sputum culture negative results both at the end of the TB treatment and at the previous occasion.
- The Panel Physician and the Panel Radiologist shall compare the CXR taken at this application with that taken at the previous one, and take the findings of the interview and the physical examination into consideration. And when the Panel Physician determines that the Applicant no longer has active TB, the Certificate may be issued. If undetermined, the Panel Physician may request the Applicant to submit another set of three sputum specimens (see section 7).

TB treatment provided at another TB Treatment Facility

- When it is agreed that the Applicant will receive TB treatment at another TB Treatment Facility, the Panel Physicians shall provide a referral letter (Annex G) to the Applicant.
- The Panel Physician must make sure that the TB Treatment Facilities provide TB treatment in accordance with the WHO treatment guideline as well as any national TB protocol, and other requirements of TB Treatment Facilities (See Section 3).
- The Panel Physician should share the results of culture and drug susceptibility test with the physician in charge of TB treatment of the Applicant in the TB Treatment Facility immediately after their results become available.
- The Panel Physician should request the TB Treatment Facility to complete and send a diagnostic report (Annex Ia) to the referred Panel Physician after the diagnosis of active TB.
- Either the Panel Physician who received the report or the physician at the TB Treatment Facility will notify the authorities responsible for TB control about the case of active TB, according to the national TB guidelines.
- The Panel Physician should request the TB Treatment Facility to complete and send a TB treatment completion report (Annex Ib) addressed to the Panel physician after the completion of the treatment of the active TB.
- The Applicant should restart the TB screening process at the same Panel Clinic, but not within six months of the previous examination, at an additional fee (the standard test fee). Under exceptional circumstance whereby the initial Panel Clinic is no longer able to provide the screening services, the Applicant may choose another Panel Clinic.
- Once the Applicant has completed the full course of TB treatment, the Applicant may then restart the TB screening process, but not within eight months of the previous examination, at an additional fee (the standard test fee).
- The Panel Physician shall restart the TB screening process after confirming that the TB Treatment Completion Report (Annex Ib) indicates at least two sputum culture negative results both at the end of the TB treatment and at the previous occasion.
- The Panel Physician and the Panel Radiologist shall compare the CXR taken at this application with that taken at the previous one, and take the findings of the interview and the physical examination into consideration. And when the Panel Physician determines that the Applicant no longer has active TB, the Certificate may be issued. If undetermined, the Panel Physician may request the Applicant to submit another set of three sputum specimens. (see Section 7)

9 Validity period of certificate

The Certificate shall be valid for 180 days from the date of the CXR.

When the Applicant meets either of the following conditions, the validity period of the Certificate will be reduced from 180 days to 90 days;

- 1) One of more family member(s), who live together with the Applicant, had been diagnosed with active infectious pulmonary TB within two months from the date of the CXR.
- 2) The Applicant has shared the same enclosed airspace or household or other enclosed environments with a person who had been diagnosed with active infectious pulmonary TB within two months from the date of the CXR for a prolonged period (days or weeks).

ACKNOWLEDGEMENTS

This Technical Instructions have been written by the Government of Japan with reference to the UK tuberculosis screening Technical Instructions, Public Health England, September 2013, version 6, and March 2019, version 7. The Government of Japan is grateful for the comments and advices given by the International Organization for Migration (IOM) in preparation for the Technical Instructions.

Annex A Administrative arrangements

- Each medical facility that intends to conduct the pre-entry TB screening needs to be designated as a Panel Clinic from the Government of Japan. Accordingly, all physicians who are to be in charge of the screening (“Panel Physician”), radiologists who are to interpret CXR (“Panel Radiologist”) and laboratories which are to perform laboratory testing (“Panel Laboratory”) need to be registered in advance by the Government of Japan. The information and forms necessary for receiving designation from the Government of Japan as a Panel Clinic are separately determined. In case of any change(s) made to the list of registration, the Panel Clinic shall notify the Government of Japan promptly.
- Panel Physicians must have a valid medical doctor license under the law of the country concerned and have enough experience in diagnosing TB (preferably 5 years or more experience).
- Panel Radiologists must have a valid medical doctor license under the law of the country concerned and have enough experience in interpretation of chest radiography.
- Radiological technologists and medical technologists must have a valid license under the law of the country concerned and have enough experience in taking chest radiography and laboratory examinations, respectively.
- Panel Laboratories registered by the Panel Clinic must receive external quality assurance approved by the Government of Japan.
- TB Treatment Facilities shall perform TB diagnosis and treatment appropriately on the bases of WHO or the national guidelines for TB diagnosis and treatment and with the use of drugs and devices under good quality assurance in accordance with the WHO’s recommended standards.
- Panel Physicians must comply with the code of conduct in that country.
- The Panel Physician should comply with the service regulations in the country concerned.
- The Panel Clinic must submit a latest list of the issued Certificates at least once a week and a summary report twice a year (forms will be specified separately). It must respond to audit requests by the Government of Japan. It also must submit data necessary for assessment and monitoring of the screening (e.g., medical record, CXR, laboratory examination results), and data necessary to follow up on the Applicant after entering to Japan (e.g., passport number, identification number), when requested by the Government of Japan or the relevant organization conducting audit designated by the Government of Japan.
- The Panel Clinic shall securely retain the CXR, the medical record, Informed Consent Forms, as well as all laboratory results, referral letters and details of treatment appropriately for at least three years and make them available when the Government of Japan or the relevant authorities request them.
- A copy of the CXR, the radiology report, the medical record form, and referral letter shall be provided at predefined fees upon referral of the Applicant (Annex G).
- Panel Physicians should comply with the latest Technical Instructions at their responsibility in conducting pre-entry TB screening by the Government of Japan.

- The Government of Japan, or relevant organizations which the Government of Japan directs, may evaluate the Panel Clinic and the registered laboratory through auditing the processes of the TB screening through a visit and assessment of the submitted data of TB screening. The Government of Japan may guide the Panel Clinic based on the results of audits and evaluations, and the Government of Japan can request the Panel Clinic to remove the registered Panel Physicians, Panel Radiologists, radiological technologists, medical technologists, or Panel Laboratories. The Government of Japan can also remove the Panel Clinic based on the results of audits and evaluations.

Costs

- The Applicant shall be responsible for the cost of pre-entry TB screening including, but not limited to, the administration, counselling, examination, CXR, and laboratory testing, and, where relevant, the issuance of the Certificate.
- Cost of the screening mentioned above shall not include the cost of any treatment for active TB.
- Cost of the screening that an applicant is charged shall be categorized by age (under 5 years old, children aged from 5 to 14 years old, and aged 15 years or over) and be the same amount regardless of types of examination in the same Panel Clinic.
- The amount charged for the copy of the examination reports, CXR reports, or any other information for the screening process, shall be determined in advance.
- The amount charged for the screening shall be in line with the accepted standards of the country.
- The Panel Clinics shall inform the Government of Japan of the full charge they intend to claim from the Applicant including any disbursements, and immediately inform the Government of Japan of any changes. If the Government of Japan determines that there is a significant difference in expenses for the screening at Panel Clinics in the same country, the Government of Japan may ask for a correction.

Annex B: Radiographic Technical Detail

1. Radiographic techniques

- All CXRs should be taken in the postero-anterior (PA) projection to reduce cardiac magnification. In correctly exposed film, the penetration should be such that one should be able to see the first four (4) vertebral bodies well (T1-T4), and the ribs, while the rest of the vertebrae should be just visible through the heart shadow.
- Routine CXRs should be taken in full inspiration.
- All CXRs should include costophrenic angles.
- Apices should be clearly seen (without overlying clavicles).
- Rotation of the chest should be avoided.
- The scapulae should be clear of the lung fields.
- The distance of the CXR tube to the film should be 4.5-6.5 feet (140-200 cm).
- Ensure that the artefacts are excluded.

2. Special views

- An apical lordotic view and a lateral decubitus view should be done, if necessary.
- For children under 15 years of age, lateral views should be done in addition to PA view.

3. Radiation safety

Observe:

- Routine use of lead shielding for all Applicants and double shielding for children and pregnant women.
- Selection of correct film size.
- Not performing additional CXRs or scans unless clinically indicated.

4. CXR image identification

- The CXR image must bear the date of the CXR, the Applicant's name in English, and the name of the clinic. The Gregorian calendar should be used.

5. Women

- The physician must explain to all female Applicants that appropriate radiation safety is secured. The Physician has an ethical obligation to ensure that these Applicants are adequately protected. Be vigilant in avoiding unnecessary radiation exposure. For considerations in pregnant women, see Section 3. "2) Screening categories and processes".

6. Children

- Radiation exposure should be kept to a minimum. Film size should be adequate to include the chest only, and abdominal shielding should be used.

7. Others

- Abdominal shielding should be properly used.
- Privacy of the Applicants should be respected.
- Management of belongings should be properly carried out to avoid the loss of valuables.
- CXR should be digitally captured and the CXR image data should be digitally managed.

Annex C Radiological interpretation of CXRs

1. Film examinations and reports

- The correct name, date, and anatomical side markers should be included.
- Look at the so-called hidden areas with the postero-anterior view:
 - Behind the heart,
 - Apices,
 - Costophrenic angles,
 - Both hila,
 - Paratracheal regions, and
 - Below the diaphragms.
- Sometimes a nodule in the lower zones may be difficult to differentiate from a nipple shadow. Repeat CXR with nipple markers to confirm.
- The extent and likely activity of any disease present should be described, and any necessary further investigations recommended.
- Panel Radiologists should report all abnormalities in the CXR film and their possible interpretation and cause.
- If significant abnormalities, such as changes suggestive of active TB, are detected, the Panel Radiologist should report to the Panel Physician immediately.

2. Requirements for examining radiologists

Panel Radiologists must ensure:

- They accurately record the date and place of examination, the name of the Applicants, and the results of their radiological examination thoroughly with any additional investigation which may have been performed. The Panel Radiologist's name also must appear clearly.
- When reading CXR on a monitor screen, the Panel Radiologist must use high resolution diagnostic monitor (>3 MBP).
- The Panel Radiologist acknowledges responsibility for the integrity and quality of the radiological examination process.
- The Government of Japan, or others that they authorize or direct, may audit all or part of radiological examinations and any evidence of failure to maintain integrity and quality of the examination will result in possible revocation of registration as a Panel Radiologist.

3. Recording of radiological findings

If any of the following abnormalities are present, radiologists are required to annotate their reports with the following numerical codes;

MINOR FINDINGS

- 1.1 Single fibrous streak/band/scar
- 1.2 Bony islets
- 2.1 Pleural capping with a smooth inferior border (<1cm thick at all points)
- 2.2 Unilateral or bilateral costophrenic angle blunting (below the horizontal)
- 2.3 Calcified nodule(s) in the hilum / mediastinum with no pulmonary granulomas

MINOR FINDINGS (OCCASIONALLY ASSOCIATED WITH TB INFECTION)

- 3.1 Solitary Granuloma (< 1 cm and of any lobe) with an unremarkable hilum
- 3.2 Solitary Granuloma (< 1 cm and of any lobe) with calcified / enlarged hilar lymph nodes
- 3.3 Single / Multiple calcified pulmonary nodules / micronodules with distinct borders
- 3.4 Calcified pleural lesions
- 3.5 Costophrenic Angle blunting (either side above the horizontal)

FINDINGS SOMETIMES SEEN IN ACTIVE TB

- 4.0 Notable apical pleural capping (rough or ragged inferior border and/or ≥ 1 cm thick at any point)
- 4.1 Apical fibronodular / fibrocalcific lesions or apical microcalcifications
- 4.2 Multiple / single pulmonary nodules / micronodules (noncalcified or poorly defined)
- 4.3 Isolated hilar or mediastinal mass / lymphadenopathy (noncalcified)
- 4.4 Single / multiple pulmonary nodules / masses ≥ 1 cm.
- 4.5 Non-calcified pleural fibrosis and / or effusion.
- 4.6 Interstitial fibrosis / parenchymal lung disease / acute pulmonary disease
- 4.7 Any cavitating lesion OR “fluffy” or “soft” lesions felt likely to represent active TB

OTHER SIGNIFICANT FINDINGS (including non-TB findings such as mastectomy, bony lesions etc.)

- 5.0 ()

Annex D Sputum collection

Administrative arrangements

- Confirm the identity of the Applicant.
- Accurate specimen identification using non-removable labels.
- Explain the collection procedure to the Applicant.
- Use appropriate disposable equipment.
- Safe storage and disposal of clinical waste.

Sputum collection

- A sufficient amount of sputum specimen (4 ml at least)
- Preferably early morning specimens
- Three specimens must be collected at least 24 hours apart, preferably on consecutive days
- Must be directly supervised in the laboratory which has been registered by the Panel Clinic. The screw-capped container should be used for sputum collection.
- Must be collected in a safe environment and not brought from home
- Applicants should rinse their mouth with purified water before providing a sputum specimen. Check sputum collected, not just saliva.
- The collector or the supervisor of the laboratory or the laboratory technician preparing the specimen can discard any specimen found to be saliva and not sputum. In this case, the applicant needs to return the following day for collection.
- All Applicants need to be instructed to take three deep breaths, and on the fourth deep breath to cough. A cough should use an abdominal contraction and not be just from the upper chest or throat.
- The collector needs to listen to the Applicants coughing to ensure that a cough comes from the stomach and not from the chest or throat. If an Applicant continues to cough from the throat or is unable to cough from the stomach, they should be asked to return the following day.
- Applicants must not clear their nasal passages into the back of their throat and present this as sputum specimen.
- Specimens must never be pooled.

Use of induced and aspirated sputum

- For Applicants who have difficulty producing sputum, there are several methods of obtaining a specimen. Inhalation of an aerosol of sterile hypertonic saline (3–6%), usually produced by an ultrasonic nebulizer, can be used to stimulate the production of sputum. Aspiration of sputum is also available. Sputum induction and aspiration can be used for children as young as 3 years old.
- A gastric aspirate can be used for all ages and may be especially helpful for young children when sputum specimen is difficult to obtain.

Specimen handling

- The collector should be wearing an appropriate mask (N95) and well-fitting gloves during the collection process.
- Specimens should be sent to the laboratory in a metal container with a lid that can be sealed. All specimens need to arrive at the laboratory within 4 hours of collection. If the sputum specimen cannot be sent off to the laboratory within one hour, they must be refrigerated (no freezing).
- If specimens need to be transported to another site, they must be sent as soon as possible in a cold container containing ice packs.
- Specimens should be in a rack to prevent spillage and be protected from heat at all times. Specimens must never be frozen.

Safety measures

- It is preferred that collection take place outside in a sunny, well-ventilated area. The place should be private and free of passersby and onlookers to protect the privacy of the Applicant.
- The waiting area should be separated from the collection area and Applicants should be allowed to sit before collection and to read the collection technique instructions.
- All collectors must wear an appropriate mask (not surgical mask but N95) and well-fitting gloves for the process.
- If specimens must be collected inside, they must be collected in a booth or room with negative airflow. There should be 12 to 18 complete room air changes per hour. A small strip of single layer tissue paper can be placed on the door of the booth, and if the paper moves 45 degrees towards the door, adequate ventilation is provided.
- Disinfectant solutions based on phenol or alcohol can be used to disinfect the surfaces of the booth.
- Ultraviolet light can also be used provided that it is cleaned once a week to prevent dust build-up and that the wavelengths of 254 nm are emitted. The UV light needs to be on for one hour after work has finished in the booth. It must be noted that this only disinfects the surfaces in the booth and benches should be kept to a minimum area, and the booth must be free of all other materials. UV light should be replaced regularly in accordance with the manufacturer's instructions.

Sputum specimen processing

- Sputum specimens should be centrifuged before smears are performed. Standard preparation method according to WHO guidelines or National TB protocol may be applied.
- Liquid culture and solid culture should be observed for 6 weeks and for 8 weeks, respectively, under suitable conditions.
- It is preferred that the combination of liquid culture and solid culture is used. When only solid culture is used, two tubes should be applied to each specimen.
- Either of the following 3 combination patterns is preferable:
 - One liquid culture tube as well as one solid culture tube will be applied to each of the three sputum specimens, i.e., 3 liquid culture tubes and 3 solid culture tubes will be used together.

- One liquid culture tube will be applied to two (either of the first, the second, or the third) sputum specimens, then two solid culture tubes will be applied to the other sputum specimen, i.e., 2 liquid culture tubes and 2 solid culture tubes will be used together.
- One liquid culture tube will be applied to one (either the first, the second, or the third) sputum specimen and two solid culture tubes will be applied to each of the two other sputum specimens, i.e., 1 liquid culture tube and 4 solid culture tubes will be used together.
- Both of the following 2 combination patterns are acceptable:
 - Two solid culture tubes will be applied to each of the three sputum specimens, i.e., 6 solid culture tubes will be used together.
 - One liquid culture tube will be applied to each of the three sputum specimens, i.e., 3 liquid culture tubes will be used together.

Annex E Consent Form

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAM

Name of the Applicant:
Date of birth (mm/dd/yyyy):
Location of the Panel Clinic:

Applicant's Declaration:

I understand that:

- I am required to undergo testing for active tuberculosis (TB), involving an interview, physical examinations, chest X-ray and possibly sputum tests, before applying for the Certificate of Eligibility or visa for mid to long-term stay in Japan;
- If my chest X-ray is abnormal, I will receive individual counselling and an explanation of the further testing procedures.
- If my chest X-ray is abnormal, and changes are suggestive of pulmonary TB, regardless of whether these changes are old or new, or if there are other clinical reasons to suspect pulmonary TB, I will have to provide three sputum samples which will be tested for TB with smear (or any of the WHO recommended nucleic acid amplification tests (NAATs), e.g., Xpert®MTB/RIF or TB-LAMP) and culture. I understand it may take up to ten weeks to receive the results of sputum cultures.
- If sputum samples are necessary, I will be required to return for sputum collection on three consecutive mornings starting within seven (7) days of my chest X-ray. If I fail to return within seven (7) days, I will forfeit the opportunity to obtain a Certificate.
- If the smear (or any of the WHO recommended NAATs) or culture shows the presence of TB bacteria, I will be referred for TB treatment. TB Treatment shall be at my own expense; I will inform the TB treatment medical facility of any close family contacts, who may need evaluation for TB.
- I have the right to refuse to undergo the TB assessment procedure and TB treatment but understand that such action of refusal may adversely obstruct my application for the Certificate of Eligibility / visa for mid- to long-term stay.
- The identification must be a valid passport. If I do not have a passport, an official identity card issued in my home country would work as an alternative.
- I understand that the physician has the final decision about whether I receive a Certificate.

Female applicants

All female applicants will be asked about their last menstrual period to identify applicants who may possibly be pregnant:

- If I could be pregnant, I will be offered alternatives; 1) I can postpone the CXR (and TB clearance) until after delivery or 2) a chest X-ray with a protective shield.
- I acknowledge that a CXR can carry a risk for the unborn child, but that this risk is quite small in the second and third trimester.
- I am therefore advised to consult the physician and may wish to consult my gynecologist to understand the risks before I take a CXR.
- If I decide to submit to a CXR, it shall be at my own risk.

I hereby:

- consent to undergo TB testing;
- authorize you and your designated laboratory to store all relevant personal information collected during the assessment process, including health records and CXR;

- authorize you and your designated clinics to share my details and assessment results with the Government of Japan.
- authorize you to share my assessment results with the health authorities of my country of residence, where my country's laws require this.
- release and hold harmless the Government of Japan and you from any liability for loss, any injury suffered or other harm during, or as a result of, the TB assessment procedures.

I have read this consent form or had it translated for me. I was invited to ask questions to clarify what was not clear to me. Upon signing, I declare that I have understood the content of this declaration.

Applicant's signature:

Date (mm/dd/yyyy):

Please print your name:

For children, or adults without the mental capacity to give consent,

I confirm that I am the parent or legal guardian of the Applicant and also confirm that I give my consent.

Signature:

Date (mm/dd/yyyy):

Please print your name:

Relationship to applicant:

For adults who are not able to physically sign the form,

I confirm that I am an independent witness and the applicant has given their consent orally or by other non-verbal means.

Signature:

Date (mm/dd/yyyy):

Please print your name:

Relationship to applicant:

Statement of interpreter (if required),

I have translated the content of this document for the applicant to the best of my ability and in a way in which I believe s/he can understand.

Signed:

Date (mm/dd/yyyy):

Please print your name:

For female Applicants who might be pregnant,

I confirm that I have had the risks of having a chest radiography (CXR) in pregnancy explained to me and I wish to carry on with the CXR.

Signed:

Date (mm/dd/yyyy):

Please print your name:

Statement of Physician (if required),

I have explained the content of this document to the applicant and confirm that the applicant has declined to go ahead with the assessment.

Signed:

Date (mm/dd/yyyy):

Please print your name:

Annex F Japan pre-entry TB screening program medical record

Symptom screen, history of contact with TB and discretionary medical examination (For all Applicants)

For all Applicants;

- Do you have any history of previous TB?
- Has anyone in your household been diagnosed with TB in the last 2 years?
- Do you have any history of recent contact with a case of active pulmonary TB (shared the same enclosed airspace or household or other enclosed environments for a prolonged period for days or weeks)?
- Do you have any history of or are you currently immune compromised (HIV infected, chronic renal failure, malignant tumors, etc.)? Do you have any history of using immunosuppressant (steroids, anti-cancer drugs, rheumatic drugs, etc.)?

Symptom Screen

Has the Applicant (or their child) had any of the following symptoms in the last three months?

- Cough
- Sputum expectoration
- Hemoptysis
- Night sweats
- Weight loss
- Fever

Physical Examination (at the discretion of the physician).

- Chest auscultation (breath sound)
- Examinations of the neck (inspection, palpation)
- Other examinations that the Panel physician judges necessary.

Panel Physician's signature:

Date (mm/dd/yyyy):

Please print your name:

Annex G Referral letter for Applicants thought to have active tuberculosis

Dear Colleague,

Name of the Applicant:		
Date of birth (mm/dd/yyyy):	<input type="checkbox"/> Male	<input type="checkbox"/> Female
Location of the Panel Clinic:		

I refer to you the above-mentioned Applicant who underwent tuberculosis testing as a part of application process of the Certificate of Eligibility / visa for mid- to long-term stay, and was found to have:

- X-ray signs of possible active tuberculosis:
- positive sputum smears (or WHO recommended NAATs)
- positive sputum cultures
- others ()

May I ask you to:

- monitor and further investigate as appropriate
- undertake contact tracing as required
- initiate TB treatment as indicated

by following the national policy and WHO guidelines.

Upon the TB diagnosis and the completion of the TB treatment, provide us a diagnosis report (Annex Ia) and a TB treatment completion report (Annex Ib) with the following information.

- TB diagnosis (Annex Ia): TB diagnosis, laboratory results, the date TB treatment started, anti-TB medicines, and other relevant information.
- TB treatment (Annex Ib): TB treatment regimen (drugs, doses, frequency, total number of doses, treatment period), complications, adherence, results of pertinent investigations, treatment outcome, recommendations, and other relevant information.

If it turns out that the Applicant does not have active TB, kindly provide us immediately with a diagnosis report (Annex Ia) with the following information included.

- Diagnosis (Annex Ia): Name of the diagnosis made, relevant test results, reasons why active TB is ruled out, and other relevant information.

Please note that these reports are required for future applications for the Certificate of Eligibility /visa.

Thank you in advance for your kind cooperation.

Yours truly,

Name of the Panel Clinic:

Panel Physician's signature:

Date (mm/dd/yyyy):

Please print your name:

Annex H TB Clearance Certificate

JAPAN Pre-Entry Tuberculosis (TB) Screening Clearance Certificate

Affix Photo (passport size)	Certificate No. : (証明書番号)	Application Date : (dd/mm/yyyy) (申請年月日)			
	First Name(s) ^{*1} : (名)	Middle Name(s) ^{*1} : (ミドルネーム)	Family Name ^{*1} : (姓)		
	Date of Birth : (dd/mm/yyyy) (生年月日)	Gender : (性)	Male (男)	Female (女)	Others (その他)
	Passport No. : (パスポート番号)	Nationality : (国籍)	Country of Issue: (パスポート発行国)		
	Passport Expiration Date : (dd/mm/yyyy) (パスポート有効期限)	Age (at the date of application) : (申請日における年齢)			
	*1 As shown in passport (パスポートに記載のとおり)				

Contact history (Yes No) (接触歴)	Chest X-ray findings (Positive Negative) (胸部レントゲン)	Date of chest X-ray (dd/mm/yyyy) (撮影年月日)
Past history (Yes No) (既往歴)	Sputum test (Positive Negative) (喀痰検査)	Name of radiologist : (放射線科医の氏名)
Symptoms/signs (Yes No) (症状・兆候)	*Test of past TB infection (Tuberculin Skin Test (TST) Interferon- Release Assay (IGRA)) (結核既感染の検査)	*Report of diagnosis (Yes No) (診断報告書の有無)
	*Latent TB Infection (Yes No) (潜在性結核感染)	*Report of completion of active TB treatment (Yes No) (結核治療終了報告書の有無)

* For required applicants only

I certify that all above statements regarding to the applicant are true. (申請者に関する上記全項目が真実であることを証明します。)

I certify that the applicant is clear of active TB. (申請者が活動性結核ではないことを証明します。)

Name of Panel Clinic :
(指定医療機関名)

Date (dd/mm/yyyy) :
(年月日)

Panel Clinic No. :
(指定医療機関番号)

Signature :
(署名)

Name of Physician :
(医師の氏名)

This Certificate is valid until _____ (dd/mm/yyyy).

(証明書の有効期限)

Annex Ia Report of TB Diagnosis

The report of the diagnosis of the following patient introduced is as follows.

Date (/ /)

Name		Gender	Date of Birth (dd/mm/yyyy)		Address				
		Male Female Others							
Contact Number			Panel Clinic No.			Passport No.			
Diagnosis								Date of Diagnosis (dd/mm/yyyy)	
Pulmonary TB • extrapulmonary TB (site:) • other diagnosis (other than TB) ()									
Previous history of TB					Complication(s)				
Yes (When,) • No • Unknown					Diabetes mellitus • HIV infection • Others ()				
Microbiology test results at the diagnosis	() sputum smear		() Xpert MTB/RIF () Xpert MTB/RIF Ultra () TB-LAMP		Sputum culture		Species	Other bacteriology test results ()	
	Positive • Negative • Unknown • Not done • Others ()		Positive • Negative • Unknown • Not done • Others ()		Positive • Negative • Unknown • Not done • Others ()		TB • Undetermined • Others ()	Positive • Negative • Unknown • Not done • Others ()	
CXR findings		Cavitation: Yes • No • Unknown • Not done Other findings ()			The latest CXR date (dd/mm/yyyy)				
Treatment start date (dd/mm/yyyy)					Multidrug resistance			Yes • No • Unknown	
Drugs for treatment		INH	RFP	EB	PZA	SM	Other ()	Other ()	Other ()
Drug Susceptibility*		S • R • Unknown	S • R • Unknown	S • R • Unknown	S • R • Unknown	S • R • Unknown	S • R • Unknown	S • R • Unknown	S • R • Unknown
Daily Dose		mg	mg	mg	mg	mg	mg	mg	mg
Notes									
Name of Physician		Signature	Name of Panel Clinic or Treatment Facility / Contact Information (Address / FAX / Email, etc.)						

* S: sensitive, R: resistant

Annex Ib Report of TB Treatment Completion

The report of TB treatment completion of the patient introduced is as follows.

Date:

Name		Gender	Date of Birth (dd/mm/yyyy)		Address				
		Male Female Others							
Contact Number			Panel Clinic No.		Passport No.				
Diagnosis							Date of Diagnosis (dd/mm/yyyy)		
Pulmonary TB · extrapulmonary TB (site:)									
· other diagnosis (other than TB) ()									
Previous history of TB					Complication				
Yes (When,) · No · Unknown					Diabetes mellitus · HIV infection · Others ()				
Microbiology test results	() sputum smear	() Xpert MTB/RIF () Xpert MTB/RIF Ultra () TB-LAMP		Sputum culture	Species	Other bacteriology test results ()			
At the diagnosis	Positive · Negative · Unknown · Not done · Others ()	Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()	TB · Undetermined · Others ()	Positive · Negative · Unknown · Not done · Others ()			
1 month after	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
2 months after	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
3 months after	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
4 months after	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
5 months after	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
6 months after	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
	Positive · Negative · Unknown · Not done · Others ()			Positive · Negative · Unknown · Not done · Others ()		Positive · Negative · Unknown · Not done · Others ()			
CXR findings	Cavitation: Yes · No · Unknown · Not done Other findings ()			The latest CXR date (dd/mm/yyyy)					
Treatment start date (dd/mm/yyyy)	Treatment completion date (dd/mm/yyyy)		Treatment duration				Multidrug resistance		
			() months				Yes · No · Unknown		
Drugs for treatment	INH	RFP	EB	PZA	SM	Other ()	Other ()	Other ()	Other ()
Drug Susceptibility	S · R · Unknown	S · R · Unknown	S · R · Unknown	S · R · Unknown	S · R · Unknown	S · R · Unknown	S · R · Unknown	S · R · Unknown	S · R · Unknown
At the diagnosis	mg	mg	mg	mg	mg	mg	mg	mg	mg
1 month after	mg	mg	mg	mg	mg	mg	mg	mg	mg
2 months after	mg	mg	mg	mg	mg	mg	mg	mg	mg
3 months after	mg	mg	mg	mg	mg	mg	mg	mg	mg
4 months after	mg	mg	mg	mg	mg	mg	mg	mg	mg
5 months after	mg	mg	mg	mg	mg	mg	mg	mg	mg
6 months after	mg	mg	mg	mg	mg	mg	mg	mg	mg
	mg	mg	mg	mg	mg	mg	mg	mg	mg
Treatment Outcome	Cured · Tx completion · Deceased · Tx failure · Interrupted · Other ()								
Notes									
Name of Physician	Signature	Name of Panel Clinic or Treatment Facility / Contact Information (Address / FAX / Email, etc)							